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10/597,140

04/05/2007

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/597,140 | <b>Applicant(s)</b><br>ANSELL, KEITH H. |  |
|                              | <b>Examiner</b><br>SHERIDAN SWOPE    | <b>Art Unit</b><br>1652                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-49 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-24, drawn to a method for identifying a modulator of a rhomboid polypeptide. This is a linking invention also encompassed by Groups II, III, and V

Group II, Claims 25-27, drawn to a method for isolating/making a test compound and optionally modifying the test compound to enhance the pharmaceutical properties.

Group III, Claim 28, drawn to a method for formulating a test compound in a pharmaceutical composition.

Group IV, Claims 29, drawn to a modulator of a rhomboid polypeptide.

Group V, Claims 30-32, drawn to a method for formulating a modulator of a rhomboid polypeptide in a pharmaceutical composition, optionally modifying the modulator to enhance the pharmaceutical properties, and optionally testing the activity of the pharmaceutical composition comprising the rhomboid polypeptide modulator.

Group VI, Claims 33-43, drawn to a rhomboid protease substrate.

Group VII, Claims 44-47, drawn to a polynucleotide encoding a rhomboid protease substrate.

Group VIII, Claims 48-49, drawn to a method for obtaining a rhomboid protease cleavage product.

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This application contains claims directed to more than one sub-invention of the generic inventions. The sub-inventions are as follows.

For Groups I-III and V

Elect one specific rhomboid polypeptide (SEQ ID NO: ) encompassed by Claims 1-24

For Group I-III and V

Elect one specific rhomboid polypeptide characteristic to be modulated as encompassed by Claims 1-24, e.g., expression, activity, binding, immunogenicity, etc.

For Group I-III and V

If protease activity is elected, elect one specific rhomboid protease substrate (SEQ ID NO: ) encompassed by Claims 1-24

For Group I-III and V

Elect one of:

An in vitro/biochemical method

A cell culture method

An isolated tissue method

An in vivo method

For Group II

Elect one specific test compound (structure) encompassed by Claims 25-27

For Group II

Elect one of: (i) isolating or (ii) making

If (i) is elected, elect one specific isolation method encompassed by Claims 25-27

If (ii) is elected, elect one specific synthesis method encompassed by Claim 25-27

For Group II

Elect one of: (i) modification or (ii) no modification

If (i) is elected, elect one specific modification method encompassed by Claim 25-27

For Group III

Elect one specific test compound (structure) encompassed by Claim 28

For Group III

Elect one specific formulation method encompassed by Claim 28

For Group IV

Elect one specific modulator (SEQ ID NO: or structure) encompassed by Claim 29

For Group V

Elect one specific modulator (SEQ ID NO: or structure) encompassed by Claims 30-32

For Group V

Elect one of: (i) synthesis of the modulator or (ii) isolation of the modulator

If (i) is elected, elect one specific synthesis method

If (ii) is elected, elect one specific isolation method

For Group V

Elect one specific formulation method encompassed by Claims 30-32

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For Group V

Elect one of: (i) modified or (ii) not modified

If (i) is elected, elect one specific modification method encompassed by Claims 30-32

If (i) is elected, elect one specific pharmaceutical property encompassed by Claims 30-32

For Group V

Elect one of: (i) testing rhomboid protein activity or (ii) not testing rhomboid protein activity

If (i) is elected, elect one specific rhomboid polypeptide (SEQ ID NO: ) encompassed by Claims 30-32

If (i) is elected, elect one specific modulator (SEQ ID NO: or structure) encompassed by Claims 30-32

If (i) is elected, elect one specific rhomboid polypeptide activity to be assayed, as encompassed by Claims 30-32

If protease activity is elected, elect one specific substrate (SEQ ID NO: ) encompassed by Claims 30-32

If (i) is elected, elect one of:

An in vitro/biochemical method

A cell culture method

An isolated tissue method

An in vivo method

For Group VI

Elect one specific substrate (SEQ ID NO: ) encompassed by Claims 33-43

For Group VII

Elect one specific polynucleotide (SEQ ID NO: ) or encoding one specific polypeptide (SEQ ID NO: ) encompassed by Claims 44-47

For Group VIII

Elect one specific rhomboid protease (SEQ ID NO: ) encompassed by Claims 48-49

For Group VIII

Elect one specific rhomboid protease substrate (SEQ ID NO: ) encompassed by Claims 48-49

Applicant is required, in reply to this action, to elect a single sub-invention(s) to which the claims shall be restricted. The reply must also identify the claims readable on the elected sub-invention(s), including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The inventions listed as Groups I-VIII and sub-inventions thereof do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The technical feature linking

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Groups I-VIII and sub-inventions thereof appears to be that they all relate to rhomboid proteases.

However, rhomboid proteases were well known in the art. Moreover, Urban et al, 2001 teaches inhibitors of rhomboid protease activity (IDS; Fig 5), which anticipates Claim 29. Therefore Groups I-VIII and sub-inventions thereof share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups IV, VI, and VII do not share a special common structural and functional feature while, the methods of Groups I-III, V, and VIII do not use the same reagents or produce the same results. In addition, the methods of Groups I-III, V, and VIII do not comprise all of the methods for making or using the products of Groups IV, VI, and VIII. Accordingly, Groups I-VIII and sub-inventions thereof are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should Applicants traverse on the ground that the inventions are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is requested that Applicants cite the serial number of the Application on every page of filed documents.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652